Section 3

MAR 1 3 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
IMUBIND® tPA ELISA
Quantitative Factor Deficiency Test (per 21CFR864.7290)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013492

Submitted by:
American Diagnostica Inc.
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Greenwich, CT 06830
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Contact:
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Field Trial Coordinator
Phone: 203 661-0000

Summary Revised:
January 4, 2002

Name of the Device:
IMUBIND® tPA ELISA
Product No. 860

Classification Name(s):
864.7290 Test, Quantitative Factor Deficiency
GGP Hematology, Class II

Predicate Device:
K934314 TintElize® tPA

Intended Use:
IMUBIND® tPA ELISA is an enzyme-linked immunosorbent assay for the measurement of human tissue-type Plasminogen Activator (tPA) antigen in plasma. This kit is for *in vitro* diagnostic use.

Summary of Substantial Equivalence:

IMUBIND tPA ELISA is substantially equivalent to the commercially available predicate device (TintElize tPA, manufactured by Biopool International, Ventura, CA) in performance and intended use.

Summary of Performance Data:

Method Comparison
Method comparison studies versus the predicate device were performed with two different lots of IMUBIND tPA ELISA. The regression statistics in Table 1 indicate a positive correlation, between the IMUBIND tPA ELISA assay and the predicate device.

Table 1: Correlation (Y=IMUBIND, X=predicate device)

IMUBIND tPA ELISA	N	Regression Equation	R	Sy.x (ng/ml)	Sample Range (ng/ml)
Lot 1	286	Y=0.79x- -0.6	0.904	4.42	1.6-18.0
Lot 2	75	Y=0.83x+0.3	0.90	1.26	3.1-23.2

Precision
Precision studies evaluated intra-assay and inter-assay variability with 2 control samples run in replicates of 4 over 10 runs (N=20 per control). Assay results (ng/ml) were calculated using duplicate determinations. Three lots of IMUBIND tPA ELISA were evaluated.

Table 2: Precision

IMUBIND tPA ELISA	Mean (ng/ml)	Intra-Assay CV%	Inter-Assay CV%
Lot 1	6.8	3.7	8.9
	15.4	4.1	9.0
Lot 2	6.5	4.9	8.2
	14.9	4.2	4.0
Lot 3	5.6	6.0	6.7
	14.6	3.8	2.3

Section 4

SUBSTANTIAL EQUIVALENCE COMPARISON

A comparison table of the relevant similarities and differences between IMUBIND tPA ELISA and the predicate device:

	IMUBIND tPA ELISA	**TintElize tPA**
Intended Use	Similar	Similar
Principle and Method	Similar	Similar
Reagents	Similar	Similar
Storage and Stability	Similar	Similar
Specimen	Similar	Similar
Limitations	Similar	Similar
Expected Values	Similar	Similar
Performance Characteristics	Similar	Similar

Similar performance and values were obtained with both devices suggesting that the method difference does not affect device equivalence.

IMUBIND tPA ELISA is substantially equivalent to the commercially available predicate device (TintElize tPA, manufactured by Biopool International, Ventura, CA) in method, performance and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. John B. Berryman
Director of Regulatory Affairs
American Diagnostica Inc.
222 Railroad Avenue
P.O. Box 1165
Greenwich, Connecticut 06836-1165

MAR 1 3 2002

Re: k013492
Trade/Device Name: IMUBIND® tPA ELISA
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: II
Product Code: GGP
Dated: January 7, 2002
Received: January 10, 2002

Dear Mr. Berryman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2

STATEMENT OF INDICATIONS FOR USE

Applicant: American Diagnostica Inc.

510(k) Number: K013492

Device: IMUBIND® tPA ELISA

Indications for Use:

IMUBIND® tPA ELISA is an enzyme-linked immunosorbent assay for the measurement of human tissue-type Plasminogen Activator (tPA) antigen in plasma.

This kit is for *in vitro* diagnostic use.

Levels of tPA in plasma are known to be elevated in late stage pregnancy, myocardial infarction, atherosclerosis, and stroke.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013492

Concurrence of CDRH, Office of Device Evaluation (ODE)